K131165

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GLOBAL TECHNOLOGY CO., LTD

510(k) SUMMARY

Anker Dental Implant system

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Date prepared: Sep 12nd, 2013

Trade Name: Anker Dental Implant System

Common Name: Dental Implant

NOV 14 2013

Classification Name: Root-form endosseous dental implant

Device Classification: Class II

Regulation Number: 21 CFR 872.3640

Panel: Dental

Product Code: DZE

Predicate Device:

(1)Predicate Device Name: Dentium Co., Ltd Implantium
Manufacturer: Dentium Company Limited
510(k) Number: K041368

(2)Predicate Device Name: Osstem GS-III system
Manufacturer: OSSTEM Implant Co., Ltd.
510(k) Number: K091208

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Device Description:

Anker Dental Implant System consists of fixture, abutment (healing abutment, fixed abutment, dual abutment, angle abutment, o-ring abutment, temporary abutment) and cover screw. Fixture is made of pure titanium (grade IV) and its surface was treated by SLA (Sand-blasted, Large grit, Acid-etched) process. Diameters of fixtures are including 3.4 to 5.0 mm and lengthes are including 7.0 to 15.0 mm. Most abutments are made of titanium alloy and their diameters are including 4.0 to 7.0 mm. Temporary abutment is made of SUS316 stainless steel instead of titanium alloy. All products are sterilized as finished products.

Indications for Use:

Anker Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. It is intended for delayed loading.

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Substantial Equivalence:

	Item	Anker Dental Implant System	Osstem GS-III system	Dentium Co., Ltd Implantium
1.	**Classification**	Class II	Class II	Class II
2.	**Code or Federal Regulations**	872.3640	872.3640	872.3640
3.	**510K No.**	K131165	K091208	K041368
4.	**Design**			
5.	**Intended Use**	Anker Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. It is intended for delayed loading.	The GS III System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The GS III System is for single and two stage surgical procedures. It is not for immediate load.	The Dentium Co., Ltd Implantium is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.
6.	**Body Diameter**	3.4mm, 3.5mm, 3.8mm, 4.0mm, 4.3mm, 4.5mm, 4.8mm, 5.0mm	3.7 mm,4.2 mm,4.6 mm, 5.1mm	3.4mm, 3.8mm, 4.3mm, 4.8mm
7.	**Length**	7mm, 8 mm, 8.5mm, 10mm, 11.5mm, 12mm, 13mm, 14mm, 15mm	7 mm, 8.5 mm, 10mm, 11.5 mm, 13mm, 15mm	8 mm, 10 mm, 12mm, 14mm
8.	**Surface**	S.L.A. (Sand-blasted, Large grit, Acid-etched surface)	RBM (Resorbable Blasting Media)	S.L.A. (Sandblasting with large grit and acid etching)

9.	**Sterilization**	γ-ray (Radiation)	γ-ray (Radiation)	γ-ray (Radiation)
10.	**Material**	Titanium	Titanium	Titanium
11.	**Abutment angulations**	0, 17 deg	0, 17 deg	0, 15, 25 deg
12.	**Material of Abutments**	Titanium Vanadium Alloy	Titanium Vanadium Alloy	Titanium Vanadium Alloy

Comparing to the predicate devices, Dentium Co., Ltd Implantium (510K No. K041368) and Osstem GS-III system (510K No. K091208), Anker Dental Implant System is equivalent in surface treatment, intended use, method of operation, material and design.

Non-clinical Testing:

Non-clinical test was used to support the decision of safety and effectiveness.

Non-clinical testing consisted of performance of testing in accordance with the FDA guidance "Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments." The results of the non-clinical testing demonstrate that the Anker Dental Implant System is substantially equivalent to the predicate devices.

Overview for all non-clinical testing:

Testing Item	**Reference**
Compressive forces and Fatigue tests	ISO14801
Compatibility test of dental implant/abutment interface	N/A
Corrosion test	ASTM G3-89
Residual of Acidic Substances Test	ISO10993-12
Biocompatibility test	ISO10993-3 ISO10993-5 ISO10993-6 ISO10993-10 ISO10993-11 Pharmacopeia US OECD guideline #473

	OECD guideline #474
Sterilization Validation of Gamma Irradiation	ISO11137-1
Shelf life Validation	ASTM F88/F88M-09 ASTM F1140-07 ASTM F1929-98 ISO11737-2

Clinical Testing:

Non-clinical test was used to support the decision of safety and effectiveness.

Conclusion:

The evaluation of the Anker Dental Implant system does not raise any additional concerns regarding safety and effectiveness and Anker Dental Implant system may therefore be considered substantially equivalent to their predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 14, 2013

Alliance Global Company Technology Company, Limited
Ms. Yayuan Chang
Manager
2F., No.92, Luke 5th Road
Luzhu District, Kaohsiung City 82151
TAIWAN (R.O.C.)

Re: K131165
Trade/Device Name: Anker Dental Implant System
Regulation Number: 21 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: October 4, 2013
Received: October 7, 2013

Dear Ms. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Evaluation
Center for Devices and
Radiological Health

Enclosure

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GLOBAL TECHNOLOGY CO., LTD

Indications for Use

510(k) Number: K131165

Device Name: Anker dental implant system

Indications for Use:

Anker Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. It is intended for delayed loading.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
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